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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,058	03/17/2004	Anuj Chauhan	T2315-908542US02	1707

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MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
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MCLEAN, VA 22102-3833

EXAMINER	
HAGOPIAN, CASEY SHEA	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
08/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,058	CHAUHAN ET AL.	
	Examiner	Art Unit	
	Casey Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/15/2004 5/5/2006 11/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

Receipt is acknowledged of applicant's Information Disclosure Statements filed 6/15/2004, 5/5/2006 and 11/13/2006.

The information disclosure statement filed 6/15/2004 fails to fully comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; **each non-patent literature publication** or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "optically transparent" (see page 8 of Specification), does not reasonably provide enablement for a contact lens having nanoparticles dispersed therein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification explains that the nanoparticle size and loading or directly dependent on the refractive index of the

contact lens and the term, "optically transparent" is defined as the transparency equivalent to that of pHEMA or other material employed as a contact lens (page 8). The word substantially however is not found in the explanation. It is suggested that applicant incorporate the limitations of claim 2 into claim 1, however the word "substantially" should be removed form the phrase "substantially optically transparent".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 2, 6, 8, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "said lens" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. For proper antecedent basis it is suggested that applicant replace the phrase with "said contact lens".

Regarding claim 6, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 8 recites the limitation "said encapsulation material" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation, "said ophthalmic drug is substantially saturated aqueous solution of said ophthalmic drug". The examiner does not understand said limitation as written. Would the limitation be clearer if written, "said ophthalmic drug is substantially saturated **with an** aqueous solution of said ophthalmic drug"?

Claim 12 recites the limitation "kit of claim 12" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101/112

Claim 12 provides for the use of a kit, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-8 and 14 of copending Application No. 10/454,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications are coextensive in scope, that is, they are drawn to a drug delivery system comprising a contact lens containing nanoparticles that are dispersed therein. The claims in both applications also claim specific limitations regarding, optical transparency, the particular amount of nanoparticles, and particular ingredients and formulations. Also, claim 14 in both applications are drawn to an article of manufacture comprising said drug delivery system. Claim 1 of the copending application includes a particle size that the instant application does not. However, the instant application includes other limitations that indicate that the size of the nanoparticles needs to be a particular size in order for the contact lens to be "optically transparent". Thus, it would have been well within the knowledge of one of ordinary skill in the art to be able to obtain a particle size range within the nanometer range without undue experimentation to produce an optically transparent lens. One would have reasonably expected a drug delivery system comprising a contact lens containing nanoparticles capable of treating the same ocular infections/disorders/diseases as the copending application. Therefore, the instant

claims would have been obvious to one skilled in the art at the time the invention was made over the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 9, 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Resnick (US 2002/0141760 A1).

Resnick teaches a contact lens containing nanospheres that are incorporated directly therein (paragraphs 0003 and 0006). Resnick further teaches methods of incorporating drugs and therapeutic agents into the contact lens for the purpose of drug delivery to the eye (paragraph 0019 and claim 2) as well as a kit (title; fig. 3). Resnick refers to US patents 5,891,932 and 4,865,439 in paragraph 0006 for their teaching of typical contact lenses that Resnick uses as starting materials. Said patents teach soft

contact lenses and incorporation of 2-hydroxyethylmethacrylate as well as storing the lenses in saline solution.

Resnick is silent to the phrase "optically transparent", however the definition of said term in applicant's specification states, "a degree of transparency equivalent to that of p-HEMA or other material employed as a contact lens". The materials taught in Resnick read on said definition.

Thus, the teachings of Resnick render the instant claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Resnick (US 2002/0141760 A1).

Resnick teaches the elements discusses above.

Resnick is silent to the particulars of the kit claimed in the instant claims.

It is well within the knowledge of one of ordinary skill in the art to include a kit or article of manufacture because they provide a convenient mechanism to disperse products to consumers. Additionally, labels containing indications, directions, warnings, etc. are mandated. A practitioner would reasonably expect a kit comprising the drug delivery system of Resnick to provide a convenient mechanism to disperse the product to consumers as well as inform the consumer of indications, directions, and so on. Therefore, in Resnick it would have been obvious to one of ordinary skill in the art to package and label delivery system in a kit or article of manufacture.

It is also well within the knowledge of one of ordinary skill in the art to include a drug-saturated solution in the kit so the drug does not diffuse out of the contact lens are become diluted. A practitioner would reasonably expect the contact lens to have a therapeutically effective amount or concentration of drug. Therefore, in Resnick it would

have also been obvious to one of ordinary skill in the art to include a drug-saturated solution in a kit or article of manufacture.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Casey Hagopian
Examiner
Art Unit 1615

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GROUP 1500